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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,593

08/22/2003

Donald R. Thompson

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210 7590 09/18/2008  
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EXAMINER

MCMILLIAN, KARA RENITA

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/646,593	<b>Applicant(s)</b> THOMPSON, DONALD R.	
	<b>Examiner</b> KARA R. MCMILLIAN	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-48 is/are pending in the application.
- 4a) Of the above claim(s) 35-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/17/2003</u> .  | 6) <input type="checkbox"/> Other: _____                          |

Detailed Action

Claims 1-34 are cancelled. Claims 35-48 are pending.

***Election/Restrictions***

Applicant's election with traverse of Group II (claims 42-48) in the reply filed on November 3, 2006 is acknowledged. The traversal is on the ground(s) that there is not a serious search burden on the examiner. This is not found persuasive because the restriction was based upon two distinct methods namely a method preventing the development of exostosis and a method alleviating pain associated with the development of exostosis. As set forth in the restriction requirement a method of alleviating pain associated with a condition and a method preventing the development of a condition are two distinct inventions, requiring distinct and non-related searches.

Applicant's election without traverse of alendronate as a species of a bisphosphonate in the reply filed on November 3, 2006 is also acknowledged.

Claims 35-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim.

The requirement is deemed proper and is therefore made FINAL.

Claims 42-48 are being examined as they read on the elected species.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over LePage et al. (provided on IDS-L'emploi d'un bisphosphonate (APD) dans la prevention des exostoses chez le poney Shetland Etude preliminaire, 1988, Ann. Med. Vet., 132, pp. 391-399).

Claims 42-48 of the instant application claim a method of alleviating pain associated with the development of skeletal exostosis of the third metacarpus or metatarsus in horses comprising the administration of alendronate.

LePage et al. teach, in the summary on page 399, that five Shetland ponies underwent surgical lifting of the periosteal membrane of their metacarpal bone to induce exostosis. Three of the ponies received variable doses of bisphosphonate APD. Two of the ponies were controls and received no bisphosphonate. All the ponies receiving the bisphosphonate APD treatment showed no development of heterotopic ossification (the formation of bone where bone does not normally occur).

LePage et al. does not specifically teach the administration of the species alendronate. LePage et al. does not specifically teach the alleviation of pain associated with the development of skeletal exostosis.

Since LePage et al. discloses the use of bisphosphonates in the treatment of exostosis, the use of alendronate is rendered obvious in the treatment of exostosis since alendronate is a species of a bisphosphonate. An ordinary skilled artisan would be motivated to use alendronate with a reasonable expectation of success in treating exostosis since alendronate is a bisphosphonate and LePage et al. broadly teaches the use of bisphosphonates in the treatment of exostosis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize bisphosphonates (including alendronate) in a method of alleviating pain associated with the development of skeletal exostosis in horses as LePage et al. demonstrate that when bisphosphonates were used in a model of induced exostosis, heterotopic ossification did not occur. Since the pain associated with exostosis is generally associated with the impingement of a nerve by or fracture of the exostosis the alleviation or treatment of the heterotopic ossification would be expected to alleviate or treat the pain as well. Accordingly, based on the teachings of LePage et al. there is a reasonable expectation of success in treating pain associated with exostosis with alendronate since alendronate would impair the development of the exostosis and as such without the exostosis, pain due to the exostosis would not occur.

### ***Conclusions***

Claims 1-34 are cancelled. Claims 35-41 are withdrawn. Claims 42-48 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA R. MCMILLIAN whose telephone number is

Art Unit: 1617

(571)270-5236. The examiner can normally be reached on Monday-Thursday from 8:30 am- 6:00 pm and every other Friday from 8:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kara R. McMillian/  
Examiner, Art Unit 1617

KRM

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1617